

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Robert Alpern, et al.

Serial Number: 10/814,527

Filing Date: March 30, 2004

Title: METHODS AND COMPOSITIONS FOR  
TREATMENT OF ION IMBALANCES

Group Art Unit: 1614

Examiner: Phyllis G. Spivack

**CONFIRMATION NO: 6886**

FILED ELECTRONICALLY ON: NOVEMBER 6, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

Applicant(s) hereby submit(s) an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant(s) respectfully request(s) that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant(s) further request(s) that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

A.  37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d).  
-- OR --
- (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
- (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
- (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

B.  37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --
- a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C.  37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- i. a statement as specified in §1.97(e);  
-- AND --
- ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D.  37 CFR §1.97(e). Statement.

- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
- A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.

E.  Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F.  37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.  
-- OR --

Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.  
-- AND/OR --

Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G.  37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.  
-- OR --

A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: \_\_\_\_\_

Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H.  37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.  
Application in which the information was submitted: \_\_\_\_\_  
Information Disclosure Statement(s) filed on: \_\_\_\_\_  
AND  
 The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

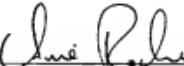
I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29329-714.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: November 6 , 2006

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| Substitute for form 1449/PTO |   |    |   | <i>Complete if Known</i> |                    |
|                              |   |    |   | Application Number       | 10/814,527         |
|                              |   |    |   | Filing Date              | March 30, 2004     |
|                              |   |    |   | First Named Inventor     | Robert Alpern      |
|                              |   |    |   | Art Unit                 | 1614               |
|                              |   |    |   | Examiner Name            | Phyllis G. Spivack |
| Sheet                        | 1 | Of | 1 | Attorney Docket Number   | 29329-714.201      |

| U.S. PATENT DOCUMENTS |                       |   |                                |  |   |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
| 14.                   |                       | US 4,605,701  | 08-12-1986                     | Haraia et al                                       |   |
| 15.                   |                       | US 5,618,530  | 04-08-1997                     | Mandeville III, et al.                             |   |
| 16.                   |                       | US 5,679,717  | 10-21-1997                     | Mandeville III, et al.                             |   |
| 17.                   |                       | US 5,693,675  | 12-02-1997                     | Mandeville, III et al.                             |   |
| 18.                   |                       | US 2003/0065090 A1  | 04-03-2003                     | Kelly et al.                                       |   |

| Examiner Initials* | Cite No. | Foreign Patent Document<br>Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages or<br>Relevant Figures Appear |
|--------------------|----------|--|--------------------------------|--|---|
| 19.                |          | JP 1998059851A   | 03-03-1998                     | Otsuka Pharmaceutical<br>Factory Inc., et al.      | X   |
| 20.                |          | JP 1998130154A   | 05-19-1998                     | Otsuka Pharmaceutical<br>Factory Inc., et al.      | X   |

| NON PATENT LITERATURE DOCUMENTS |                       |   |  |  |  |
|---------------------------------|-----------------------|---|--|--|--|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  |  |  |
| 21.                             |                       | FRIEDMAN, Eli A., Clinical Aspects of Uremia and Dialysis/ Sorbent Therapy in Uremia 671-687. (Shaul G. Massry & Alvin L. Sellers eds., 1976).  |  |  |  |
| 22.                             |                       | FRIEDMAN, Eli A., et al 1976. Combined exystarch-charcoal trial in uremia: Sorbent-induced reduction in serum cholesterol. <i>Kidney International</i> . 10: S-273-S-276.   |  |  |  |
| 23.                             |                       | IMONDI, A.R., et al. 1981. Gastrointestinal Sorbents for the Treatment of Uremia. I. Lightly Cross-Linked Carboxymethyl Polymers. <i>Ann Nutr Metabol</i> . 25(5): 311-319.   |  |  |  |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Indicate if reference considered, whether or not claimed in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of all cited and relied upon documents to replace "Any other evidence made in support of your position." See Kind Code of USPTO Patent Document at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (USPTO Standard ST. 3) \*For Japanese patent documents, the name of the office of the Japan Patent Office must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 35 if possible. \*Appended is a check mark box of English language Translation is attached.

This collection of information is required by 37 CFR 1.57 and 1.58. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is granted by 35 U.S.C. 122 and 37 CFR 1.10. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application forms to the USPTO. Your help can make a difference. If you need more time to complete the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and refer system 2.